

REMARKS

In response to the present action, Applicants have cancelled Claims 1-13 and 28, withdrawn Claims 14-27 and added new Claim 29-35. Accordingly, Claims 29-35 are pending.

Independent Claim 29 is directed to a method of ameliorating the effects of inflammation by administering one or more antibodies against M-CSF, GM-CSF, or both, for a time and in an amount to inhibit or otherwise antagonize the effects of M-CSF or GM-CSF on cells of the monocyte/macrophage lineage. The remaining claims all depend directly or indirectly from Claim 29 and further define the invention. For example, Claim 30 indicates amelioration of the inflammatory effects are evidenced by the reduced levels of proliferation, activation, growth and/or survival of cells of the monocyte/macrophage lineage. Claim 31 provides that the antibodies used in the method antagonize the effects of M-CSF, GM-CSF or both. Claims 32 and 33 are similar to original Claims 6 and 7, and indicate steps for identifying the antibodies or that the antibodies are internalized by the monocytes/macrophages, respectively. Claims 34 and 35 recite the subject of original Claim 4. Hence, Claim 34 provides that the antibodies administered in Claim 29 are administered with an agent that antagonizes the effects of u-PA. Similarly, Claim 35 now provides that the two administrations of Claim 34 includes a third administration, namely administering an agent that antagonizes other inflammatory mediators produced by cells of the monocyte/macrophage lineage. None of these claims presents new matter.

In the requirement for restriction, Applicants were required to elect one of the following 18 groups of invention:

- I. Claims 1-7, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that inhibits or antagonizes the effects of a colony-stimulating factor (CSF), wherein the agent is a CSF receptor in soluble form;

- II. Claims 1-7, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that inhibits or antagonizes the effects of a CSF, wherein the agent is a binding protein of a CSF;
- III. Claims 1-7, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that inhibits or antagonizes the effects of a CSF, wherein the agent is an antibody against a CSF;
- IV. Claims 1, 2, 4, 8-13 and 28, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that antagonizes the effects of a CSF and an agent that antagonizes the effects of uPA, wherein the agent that antagonizes the CSF is a CSF receptor in soluble form;
- V. Claims 1, 2, 4, 8-13 and 28, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that antagonizes the effects of a CSF and an agent that antagonizes the effects of uPA, wherein the agent that antagonizes the CSF is a binding protein of a CSF;
- VI. Claims 1, 2, 4, 8-13 and 28, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that antagonizes the effects of a CSF and an agent that antagonizes the effects of uPA, wherein the agent that antagonizes the CSF is an antibody against a CSF;
- VII. Claims 1, 2, 4, 8-13 and 28, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that antagonizes the effects of a CSF and an agent that antagonizes the effects of uPA and other inflammatory mediators, wherein the agent that antagonizes the CSF is a CSF receptor in soluble form;
- VIII. Claims 1, 2, 4, 8-13 and 28, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that antagonizes the effects of a CSF and an agent that antagonizes the effects of uPA and other inflammatory mediators, wherein the agent that antagonizes the CSF is a binding protein of a CSF;
- IX. Claims 1, 2, 4, 8-13 and 28, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent that antagonizes the effects of a CSF and an agent that antagonizes the effects of uPA and other inflammatory mediators, wherein the agent that antagonizes the CSF is an antibody against a CSF;
- X. Claims 14-16, directed to a composition comprising one or more molecules capable of inhibiting or antagonizing the effects of a CSF;
- XI. Claims 14-17, directed to a composition comprising one or more molecules capable of inhibiting or antagonizing the effects of a CSF and further comprising an agent that antagonizes the effects of uPA;

- XII. Claims 14-17, directed to a composition comprising one or more molecules capable of inhibiting or antagonizing the effects of a CSF and further comprising an agent that antagonizes the effects of uPA and/or other inflammatory mediators;
- XIII. Claim 18, directed to a composition comprising an antagonist of uPA;
- XIV. Claim 18, directed to a composition comprising an antagonist of uPA and an antagonist of one or more other inflammatory mediators;
- XV. Claim 19, directed to immunoreactive molecules to M-CSF and GM-CSF and an antagonist of uPA;
- XVI. Claim 19, directed to immunoreactive molecules to M-CSF and GM-CSF and an antagonist of uPA and an antagonist of one or more other inflammatory mediators;
- XVII. Claims 20-23 and 26-27, directed to a method of ameliorating the effects of inflammation in a subject by administering an agent comprising an encapsulated monocyte/macrophage interacting ligand chemically linked to the active portion of an agent capable of inhibiting or antagonizing the effects of a CSF; and
- XVIII. Claims 24-25, directed to an agent comprising an encapsulated monocyte/macrophage interacting ligand chemically linked to the active portion of an agent capable of inhibiting or antagonizing the effects of a CSF.

As indicated, and in order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group III, original Claims 1-7, now Claims 29-35, wherein the agent used to inhibit or otherwise antagonize the CSF is an antibody against a CSF; and reserve the right to file a divisional application directed to the non-elected subject matter. However, in view of the amended claims, Applicants respectfully request the Examiner to rejoin the subject matter of Groups VI and IX for examination with the subject matter of Group III.

In particular, the subject matter of Groups VI and IX is closely related to that in Group III because each group provides that the same agent inhibits or otherwise antagonizes the CSF, that agent being one or more antibodies against the indicated CSFs. The groups differ in that Group VI adds a second step of administering an agent that antagonizes the effects of u-PA, and Group

IX adds yet a third step of administering an agent that antagonizes the effects of other inflammatory mediators produced by cells of the monocyte/macrophage lineage. In this respect, Claim 34 and Claim 35 could be regarded as belonging in Group VI and IX, respectively. Given the present scope of the claims, and the fact that the Examiner indicated that the subject matter of Groups III, VI and IX are classified in the same subclass (Class 424, subclass 139.1), rejoining these groups for examination does not place an undue search burden on the Examiner –and in fact simplifies the searches since the subject matter of Group III is common to all three groups. Accordingly, Applicants request the Examiner to join at least Groups III, VI and IX, as embraced in Claims 29-35, for examination in the present application.

Moreover, this election is made with traverse with respect to all the subject matter, because even though the claims of Groups I to XVIII may be considered by the Examiner as patentably distinct from one another, it is firmly believed that the claims are sufficiently related to be properly presented in a single application.

The subject matter of Groups I-IX (original Claims 1-13 and 28), directed to methods of ameliorating the effects of inflammation in a subject, is closely related to that of Groups X-XVI (original Claims 14-19) which is directed to compositions for use in those methods. Similarly, the subject matter of Group XVII (original Claims 20-23, 26 and 27) is directed to a method of ameliorating the effects of inflammation in a subject using one of the agents of the previous groups chemically linked to a monocyte/macrophage interacting ligand, the compounds being encapsulated, whereas the subject matter of Group XVIII (original Claims 24 and 25) is directed to the encapsulated compounds used in the methods of Group XVII. Given the commonality of the subject matter here, examination of the subject matter of Groups I-XVIII does not place a serious search burden upon the Examiner.

If there are any issues outstanding after consideration of this election, the Examiner is invited to contact the undersigned to expedite prosecution of this case.

Respectfully submitted,

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